31 October 2024

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 September 2024

InhaleRx Ltd (ASX: IRX), ('**InhaleRx', 'IRX'** 'or '**the Company'**) an Australian healthcare company developing unique inhaled medicinal drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to provide its quarterly activities, cash flow report and an update of operations.

Operational highlights are as follows:

- Cash reserves at 30 September 2024: $117k.
- Net cash generated/(used) in the quarter for operating activities: ($242k).
- The Company signed a $38.5m funding agreement with Clendon Biotech Capital Pty Ltd ('**Clendon'**) on 18 October 2024 which fully covers the clinical trial costs, including the associated non-clinical work and trial drug manufacturing costs for the IRX-211 and IRX-616a drug development plans through to the completion of Phase 2 clinical trials.
- The Company lodged its Human Research Ethics Committee ('**HREC**') submission to run the Phase 2 trial on 19 September 2024 investigating the safety and efficacy of IRX211 with patients who have a Breakthrough Cancer Pain (**'BTcP'**) diagnosis. We anticipate receiving a final response to this submission in mid Q4 2024.
- A tender has been issued for the appointment of a Contract Research Organisation ('**CRO'**) for the purposes of overseeing the Phase 1 IRX616a human clinical trial in respect of Panic Disorder. The process is expected to be completed by mid-December 2024. The Company has prepared all of the information required for a Phase 1 HREC submission and all medical writing is now complete.
- The Company entered into a Loan Agreement with Peak Asset Management on 27 March 2024 with $250k to be available immediately and a further $250k draw down available in September 2024. $50k remains outstanding from the March draw down. The Company has now received $200k in respect of the September draw down, $27.5k of which was received before the end of the quarter. Despite significant attempts to access the remaining balance of $100k, there appears to be significant doubt as to whether these funds can be recovered. The compliant loan funders all elected to convert their loans to equity under the terms of the Loan Agreement on 18 October 2024 based on the 30-day volume-weighted average price (**'VWAP'**) at that time ($0.023) and were issued 17.969,880 ordinary shares.

The net cash outflow from operating activities during the quarter was $242k with the Company incurring $66k of one-off research and development expenditure in relation to its IRX211 Phase 1 clinical trial. The remaining expenditure was mainly spent on corporate costs ($136k) and investor relations ($23k).

The Company continues to apply a disciplined approach to the incurrence of operational expenditure and has proposed, subject to shareholder approval, that an equity based remuneration arrangement be

InhaleRx Limited (ACN 611 845 820)
Level 9, 505 Little Collins Street,
Melbourne, Victoria 3000
Phone: +61 3 8678 4091

introduced for the Board and CEO as a means of preserving the Company's cash reserves until such time as it has access to sufficient fresh capital. Details of this proposal are included in the Explanatory Memorandum to the Notice of Meeting for Extraordinary General Meeting which has been called for 28 November 2025.

Clendon Funding Agreement

InhaleRx has secured a funding facility of up to $38.5 million from Clendon to fully cover the clinical trial costs, including the associated non-clinical work and trial drug manufacturing costs for the IRX-211 and IRX-616a drug development plans through to the completion of Phase 2 clinical trials.

This funding will enable InhaleRx to move forward with its clinical development plans for IRX211 and IRX616a, including non-clinical data. It will also enable IRX to address the requirements of the FDA relevant to its recent IRX-616a IND application.

The funding agreement is expected to allow the Company to reach the Phase 3 pivotal stage for both IRX-211 and IRX-616a within the next 2-3 years. The facility allows for the drawdown of funding as eligible expenditure is incurred.

Once approved, the Clendon Biotech Capital facility will allow the Company to immediately activate the specification adjustment and batch manufacturing work required in the manufacture of the requisite trial drugs for the proposed IRX616a (Phase 1), and IRX-211 (Phase 2) trials.

This partnership ensures that InhaleRx can move forward with the next stages of its clinical trials and non-clinical work, including addressing the further requirements outlined in FDA feedback related to its recent IND submission for IRX-616a.

The terms of the funding agreement include a competitive interest rate of 15% per annum (capitalizing monthly), with repayment terms tied to the completion of each project. Additionally, as part of this funding arrangement, Clendon Biotech Capital will receive options in InhaleRx representing 19.9% of the ordinary shares on issue as at 18 October 2024.

The Company must repay the money owed in cash but may use the proceeds from the exercise of the Options to make the repayments.

The exercise price of the Options is the higher of:

(a) $0.025 per Option; and

(b) a price equal to 90% of the 90-day VWAP of the shares in the Company ending one business day before the date of exercise of the Option.

The facility will be secured by a General Security Deed granted by the Company in favour of Clendon Biotech Capital over all of its assets and undertaking.

An Extraordinary General Meeting has been called for 28 November 2024 for the purposes of approving the issue of 38,449,145 Options to Clendon under the funding agreement.

With this strategic support, InhaleRx is well positioned to accelerate the development of breakthrough inhaled therapies for patients with unmet medical needs.

About Clendon Biotech Capital

Clendon Biotech Capital is a Melbourne based venture capital investor which is keenly focused on small to midsize biotechnology companies in its target therapeutic areas - neuroscience, gastroenterology, oncology and anti-aging.

The Board of InhaleRx views the partnership with Clendon as a transformative step in securing the Company's ability to execute its clinical development strategy, which will further position it as a leader in the inhaled therapeutics sector.

Clinical development pathway - general up-date

The Company's core focus for the September 2024 quarter was on:

1. Seeking further input from two Key Opinion Leaders on development of the IRX-211 protocol. Based on this feedback, minor changes were made to strengthen the trial design in preparation for the IRX-211 Phase 2 HREC application. The HREC application was submitted on 19 September 2024, with a decision expected within the next 4-6 weeks.

2. Finalising all medical writing in readiness for commencing the tender process for the appointment of a CRO to oversee the Phase 1 clinical trial for IRX616a.

3. Developing an action plan for the purposes of addressing the issues identified relevant to the feedback from the FDA on the Company's IRX616a Investigational New Drug ('**IND'**) submission.

The Company's overarching goal remains to achieve a New Drug Application(s) ('**NDA**') with the FDA. IRX is committed to driving cost efficiency while delivering outcomes in the shortest time frame possible.

Pain Indication (IRX-211)

Breakthrough Cancer Pain (BTcP)

According to the 11th revision of the International Classification of Diseases, chronic cancer pain is defined as pain caused by primary cancer itself, metastases or its treatment. BTcP is described as a temporary intensification of such pain that arises either spontaneously or in connection with a particular predictable or unpredictable trigger, even when the background pain is relatively stable and well-controlled.

While the current (mainly opioid-based e.g. fentanyl) therapeutic options play a crucial role in managing pain, their prescription and use requires careful monitoring and adherence to established guidelines to mitigate the significant risks of tolerance, dependence, and opioid-related adverse events. As a result, there is a significant unmet need in the BTcP space for a non-opioid-based rapid-onset analgesic.

It is estimated that approximately half of the adult cancer population experiences BTcP at some point, this can vary based on disease progression, ranging from 39.9% in outpatient clinics to 80.5% in palliative care units[1].

There are an estimated 18.1m cancer survivors living in the US alone[2], with approximately one to two-thirds of patients with advanced cancer and chronic pain experiencing BTcP[3].

IRX211 is aiming to capture a significant share of this market due to its non-opioid nature and rapid onset of action.

IRX-211 clinical trial program update targeting Breakthrough Cancer Pain

IRX211 is a cannabinoid (dronabinol) based Active Pharmaceutical Ingredient (API) delivered via inhalation in a fixed dose designed to provide rapid onset analgesia for patients suffering with acute episodic bursts of breakthrough pain, which are generally of short duration, typically lasting minutes to hours, including BTcP.

IRX completed its Phase 1 clinical trial for IRX211 earlier in the year and reported pleasing results for pharmacokinetics (PK), safety and tolerability in healthy male and female subjects. There were also no serious adverse events throughout the duration of the study, the results of which have provided the necessary data to inform the dose required for the next stage of the drug development pipeline - the proposed Phase 2 trial.

The review of the Phase 1 CSR has allowed the Company to confidently prepare for the Phase 2 trial, with a much clearer understanding of the desired dose required. This is a critical step towards preparing for the U.S. FDA approval under the 505(b)(2) regulatory pathway, which InhaleRx aims to pursue given the unmet need for fast-acting pain management options in cancer care.

<u>Mental health indication (IRX-616a)</u>

IRX-616a clinical trial program update targeting Panic Disorder.

Panic Disorder

Panic disorder is a type of anxiety disorder characterised by recurrent panic attacks, which are sudden periods of intense fear or discomfort that may include palpitations, chest pain, and difficulty breathing. It is a common mental health condition that affects people of all ages, but it is more common in women and typically begins in young adulthood.

Some common medications used to treat panic disorder include selective serotonin reuptake inhibitors (SSRIs) and benzodiazepines.

Existing drugs like SSRI's can affect sleep, sexual function, carry drug interactions and in some cases, suicidality risk.

[1] Deandrea S, Corli O, Consonni D, Villani W, Greco MT, Apolone G. Prevalence of breakthrough cancer pain: a systematic review and a pooled analysis of published literature. J Pain Symptom Manage [Internet]. 2014 [cited 2023 Apr 11];47(1):57–76. Available from: https://pubmed.ncbi.nlm.nih.gov/23796584/

[2] https://cancercontrol.cancer.gov/ocs/statistics

[3] Davis MP. Breakthrough Pain in Cancer Patients – Characteristics, Impact, and Assessment. US Oncology Hemat 7(1):12, 2011.

The exact prevalence of panic disorder is difficult to determine, as it is often under-diagnosed and under-treated. However, it is estimated to affect approximately 3-5% of the general population.

To put this in perspective, the Global Anxiety Disorders and Depression Treatment Market size is estimated at USD 21.51 billion in 2024 and is expected to reach USD 27.87 billion by 2029[4].

Notwithstanding, there are currently no FDA approved drugs for treating Panic Disorder via inhalation.

IRX-616a clinical trial program update targeting Panic Disorder

IRX-616a is a cannabinoid (cannabidiol) based Active Pharmaceutical Ingredient (API) delivered via inhalation in a fixed dose designed to provide rapid onset relief for patients suffering with Panic Disorder, which are sudden periods of intense fear or discomfort that may include palpitations, chest pain, and difficulty breathing.

A tender has been issued for the appointment of a CRO for the purposes of overseeing a small Phase 1 safety, pharmacokinetics, and tolerability human clinical trial of IRX616a involving healthy volunteers. The process is expected to be completed by mid-December 2024.

Across the September quarter, the Company finalised all medical writing required for a HREC submission in preparation for the Phase 1 trial. It is expected that this trial will satisfy the pre-requisite requirements outlined in the response to the Company's Phase 2 HREC submission. Following this trial, the Company intends to re-submit to HREC for an approval to conduct a Phase 2 trial in Australia.

The Company also conducted a detailed review of the feedback from the FDA in relation to the Clinical Hold, following the Investigational New Drug (IND) submission. These issues were largely related to the absence of non-clinical data in support of the application which is both complex and expensive to obtain as it involves the administration of inhaled medication and will likely need to be conducted outside Australia. These requirements have now been incorporated into the Company's clinical development program for IRX616a as covered under the Clendon Capital funding arrangements.

Capital requirements

The Company's Board entered into a $500k Convertible Loan Facility ('**Facility'**) with Peak Asset Management ('**Peak**') on 27th March 2024, with the first draw down ($250k) available in Q1 2024, while the remaining draw down was scheduled to take place in Q3 2024. IRX received $200k in respect of the March draw down and has now received $200k in respect of the September draw down, $27.5k of which funds were received by the end of the September quarter.

The compliant loan funders all elected to convert their loans to equity under the terms of the Loan Agreement on 18th October 2024 based on the 30-day volume-weighted average price ('**VWAP'**) at that time ($0.023) and were issued 17,969,880 ordinary shares.

[4] https://www.mordorintelligence.com/industry-reports/anxiety-disorders-and-depression-treatment-market

$100k of the total amount available under the Facility remains outstanding. Despite numerous attempts, the Company has been unable to access these funds and the Company's Board is now of the view that there is significant doubt as to whether these funds can be recovered.

While it is expected that the Clendon funding facility will cover all necessary clinical trial costs, InhaleRx will remain responsible for funding its operational and corporate overheads as these costs are specifically outside the scope of the funding arrangement. The Company remains confident in its ability to secure the necessary additional funding to meet these working capital costs and ensure continued operational sustainability.

Payments to Directors & Related Parties

Cash payments to Directors during the September 2024 quarter totalled $8k (excluding GST) with a further $15k (excluding GST) paid as salaries to key personnel and contractors.

Use of funds

The Company received $28k from in respect of the September drawdown on the $500k Facility and an ATO net refund received of $27k related to GST.

During the quarter, funds spent on operating activities comprised:

- $66k in clinical development costs (CRO payments);
- $157k in general corporate costs including: legal (Clendon facility related) ($44k); insurance ($43k); share registry/ASX/ASIC costs ($32k); audit ($22k); CFO ($8k) and company secretary ($8k);
- $23k paid for investor relations;
- $15k in salaries paid to employees; and
- $8k in director fees.

GST is included in the amounts noted above as applicable.

The Company will provide further updates in due course.

Authorised by the Board of Directors.

For further information:
www.inhalerx.com.au

James Barrie
Phone 03 8678 4091

About InhaleRx Limited (ASX: IRX) – www.inhalerx.com.au

InhaleRx Limited is an Australian healthcare company which is developing unique medicinal drug-device products to address unmet medical needs in pain management and mental health sectors.

The overarching goal is to pursue U.S. FDA approval and registration using rapid and cost-effective regulatory pathways, such as 505(b)(2).

There is a significant economic opportunity for IRX and the Company's shareholders. The first medical indications under investigation are Breakthrough Cancer Pain ('**BTcP'**) and Panic Disorder ('**PD'**), both of which currently have limited safe and effective treatment options.

IRX holds an innovation patent and provisional patents for the nominated indications and the Company plans to continue to strengthen this position.

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